

Notice of Allowability**Application No.**

10/631,980

Examiner

TIMOTHY E. BETTON

Applicant(s)

CALHOUN ET AL.

Art Unit

1617

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 29 June 2009.
2. ☒ The allowed claim(s) is/are claims 56-85 are allowed.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: ____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date ____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date ____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date 1 sheet, 31 May 2009
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 20090731/7/31/2009
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other ____.

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DETAILED ACTION

Claims 56-85 are found allowable.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Kenton Mullins on 31 July 2009.

The application has been amended as follows:

1-55. Cancelled.

INSERT THE FOLLOWING NEW CLAIMS:

56. (New) A resorbable adhesion-inhibition membrane for inhibiting adhesions and scarring comprising a substantially uniform composition of a polymeric material, the polymeric material being capable of resorbing into a mammalian body within a period greater than 6 months and less than 24 months from an initial implantation of the adhesion-inhibition membrane into the mammalian body, the polymeric material having a biased molecular orientation in the membrane that is biased to at least one axis, with a viscosity property greater than about 1 g/dL to 3.5 g/dL and an anti-inflammatory characteristic comprising a first substantially-smooth non-porous surface, and the membrane having an opposing second surface and a thickness of about 0.001 mm to about 0.300 mm as measured between the first substantially-smooth non-porous surface and the opposing second surface.

57. (New) The membrane of claim 56, wherein the polymeric material comprises a substantially amorphous polymer.

58. (New) The membrane of claim 56 wherein the molecular orientation of a polymer of the polymeric material is biased toward one axis.

59. (New) The membrane of claim 56 wherein the molecular orientation of a polymer of the polymeric material is biased toward two axes.

60. (New) The membrane of claim 56 being about 0.010 mm to about 0.100 mm thick.

61. (New) The membrane of claim 56 being about 0.015 mm to about 0.025 mm thick.
62. (New) The membrane of claim 56 being about 0.020 mm thick.
63. (New) The membrane of claim 56 wherein the membrane has a glass transition temperature, and a thickness of the membrane increases by at least 5 times when the membrane is brought to its glass transition temperature.
64. (New) The membrane of claim 56 wherein the membrane has a glass transition temperature, and a thickness of the membrane increases by at least 10 times when the membrane is brought to its glass transition temperature.
65. (New) The membrane of claim 56 being impregnated with an additive selected from the group consisting of a chemotactic substance for influencing cell-migration, an inhibitory substance for influencing cell-migration, a mitogenic growth factor for influencing cell proliferation and a growth factor for influencing cell differentiation.
66. (New) The membrane of claim 56 being contained in a sealed sterile packaging.
67. (New) The membrane of claim 56 further having at least one thick portion, each thick portion has a length equal to or shorter than the longest length of the membrane, a width greater than about 0.5 mm, and a thickness greater than about 2 times a thickness of a central area of the membrane.
68. (New) The membrane of claim 67 wherein the thick portion protrudes from both of the two surfaces and forms at least a segment of an edge of the membrane.
69. (New) The membrane of claim 67 wherein a first thick portion forms at least a segment of a first edge of the membrane, and a second thick portion forms at least a segment of a second edge of the membrane.
70. (New) The membrane of claim 67 wherein a thickness of the membrane increases more than 2 times when the membrane is brought to its glass transition temperature.
71. (New) The membrane of claim 69 further comprising a plurality of holes disposed along the thick portion.
72. (New) The membrane of claim 56 further comprising a plurality of holes disposed along an edge of the membrane.
73. (New) The membrane of claim 56 having a viscosity property greater than about 2 g/dL.
74. (New) The membrane of claim 56 having a viscosity property of about 3 g/dL.
75. (New) The membrane of claim 56 having a non-uniform shrinking characteristic.
76. (New) The membrane of claim 56 having a directional shrinking characteristic.
77. (New) A resorbable adhesion-inhibition membrane for inhibiting adhesions and scarring, comprising a substantially uniform composition of a polymeric material extruded into a membrane, the adhesion-inhibition membrane being capable of resorbing into a mammalian body within a period greater than 6 months to 24 months from an initial implantation of the membrane into the mammalian body, the membrane having an anti-inflammatory characteristic with a viscosity property greater than about 2.5 to 3.5 g/dL, the anti-inflammatory characteristic comprising a substantially-smooth anti-inflammatory surface and the membrane being about 0.001 mm to about 0.300 mm thick as measured between the substantially-smooth anti-inflammatory surface and a second opposing surface of the membrane.
78. (New) The membrane of claim 77, wherein the polymeric material comprises a substantially amorphous polymer.
79. (New) The membrane of claim 77 further comprising at least one thick portion, the at least one thick portion having a length equal to or shorter than a longest length of the membrane, a width greater than about 0.5

mm, and a thickness greater than about 2 times the thickness of the membrane at a region other than the at least one thick portion.

80. (New) The membrane of claim 79 wherein the thick portion protrudes from both of the two surfaces and forms at least a segment of an edge of the membrane.

81. (New) The membrane of claim 79 wherein a first thick portion forms at least a segment of a first edge of the membrane, and a second thick portion forms at least a segment of a second edge of the membrane.

82. (New) The membrane of claim 79 wherein the thick portion is effective to provide rigidity to the membrane.

83. (New) The membrane of claim 79 further comprising a plurality of holes disposed along the thick portion.

84. (New) A resorbable anti-adhesive membrane comprising a substantially uniform composition of a polymeric material, the polymeric material being capable of resorbing into a mammalian body within a period greater than 6 months to 24 months from an initial implantation of the anti-adhesive membrane into the mammalian body, the polymeric material comprising a polylactide and having a biased molecular orientation in the membrane that is biased to at least one axis and a viscosity property of about 1 g/dL to 3.5 g/dL, the membrane having at least one substantially-smooth-anti-adhesive surface and being non-porous, the membrane also having a thickness of about 0.001 mm to about 0.300 mm as measured between the substantially-smooth anti-adhesive surface and an opposing surface of the membrane, wherein the membrane has a glass transition temperature and a thickness of the membrane increases by at least 5 times when the membrane is brought to its glass transition temperature.

85. (New) A resorbable anti-adhesive membrane comprising a substantially uniform composition of a polymeric material capable of resorbing into a mammalian body within a period greater than 6 months to 24 months from an initial implantation of the anti-adhesive membrane into the mammalian body, the polymeric material comprising a polylactide and having a biased molecular orientation in the membrane that is biased to at least one axis and a viscosity property that is of about 1.25 g/dL to 1.75 g/dL, the membrane having at least one substantially-smooth anti-adhesive surface and being non-porous, the membrane further having a thickness of about 0.001 mm to about 0.300 mm as measured between the substantially-smooth anti-adhesive surface and an opposing surface of the membrane, wherein the membrane has a glass transition temperature and a thickness of the membrane increases by at least 10 times when the membrane is brought to its glass transition temperature.

Reasons for Allowance

In view of applicants' cancellation of claims 1-55 via Examiner's Amendment, all outstanding rejections are herein withdrawn.

The following is an examiner's statement of reasons for allowance:

In instant claim 56, the limitation drawn to the thickness of the membrane at 0.001 mm to about 0.300 mm as measured between the first substantially-smooth non-porous surface and the opposing second surface is not fairly taught or suggested in the prior art.

Newly added claims 56-85 are found to be novel and non-obvious over the current prior art of record drawn to A resorbable adhesion-inhibition membrane for inhibiting adhesions and scarring comprising a substantially uniform composition of a polymeric material, the polymeric material being capable of resorbing into a mammalian body within a period greater than 6 months and less than 24 months from an initial implantation of the adhesion-inhibition membrane into the mammalian body, the polymeric material having a biased molecular orientation in the membrane that is biased to at least one axis, with a viscosity property greater than about 1 g/dL to 3.5 g/dL and an anti-inflammatory characteristic comprising a first substantially-smooth non-porous surface, and the membrane having an opposing second surface and a thickness of about 0.001 mm to about 0.300 mm as measured between the first substantially-smooth non-porous surface and the opposing second surface.

None of the references *supra*, either alone or together teach nor render obvious a resorbable adhesion-inhibition membrane for inhibiting adhesions and scarring comprising a substantially uniform composition of a polymeric material, the polymeric material being capable of resorbing into a mammalian body within a period greater than 6 months and less than 24 months from an initial implantation of the adhesion-inhibition membrane into the mammalian body, the polymeric material having a biased molecular orientation in the membrane that is biased to at least one axis, with a viscosity property greater than about 1 g/dL to 3.5 g/dL and an anti-inflammatory characteristic comprising a first substantially-smooth non-porous surface, and the membrane having an opposing second surface and a thickness of about 0.001 mm to about 0.300 mm as measured between the first substantially-smooth non-porous surface and the opposing second surface.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY E. BETTON whose telephone number is (571)272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1617